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June 4, 2003

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street SW  
Washington, DC 20204

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**Section 403(r)(6) Notification**

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

**Clear, Healthy Lips and Mouth Tissue**

**Healthy lips and mouth tissue may be affected by sun exposure, trauma, emotional anxiety, and high body temperature. Lysine, an amino acid, may be helpful in maintaining healthy lips and mouth tissue. Lysine also helps calcium absorption, helps collagen and tissue renewal, and aids in the production of antibodies, hormones, and enzymes.**

on the following product:

**YourLife® L-Formula® Lysine**

Very truly yours,

Leiner Health Products

  
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William Cochran, Manager of Regulatory Affairs

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